BIOSPECTRA

100 Majestic Way, Bangor, PA 18013 / www.biospectra.us

Effective Date:	22-Jan-2025	22-Jan-2028	: Date of Next Review
Prepared By:	Amy Yencho	Not Applicable	: Supersedes
QA/QC Approval:	Krista Rehrig	Carissa Albert	: Management Approval
Reason for Revision:	See Revision History in MasterControl.		

CERTIFICATE OF ANALYSIS

TREHALOSE, DIHYDRATE

BIOTECH, MEETS NF, EP, JP, LBLE, GMP

BIO PHARMA GRADE / TRED-4250

LOT: TRED-N02-0925-0024

$C_{12}H_{22}O_{11} \cdot 2H_2O$ ⅄ F.W. 378.33 g/mol. ⅄ CAS# 6138-23-4

Manufacturing Date: 09/03/25 Retest Date: 09/30/27

Manufacturing Site: 100 Majestic Way, Bangor PA, 18013

Packaging Site: 100 Majestic Way, Bangor PA, 18013

ANALYSIS		SPECIFICATION	TEST RESULT
Appearance and Color		White to Almost White Crystalline Powder	White Crystalline Powder
Assay, Anhydrous Basis (NF/EP/JP)		98.0 – 101.0 %	99.8 %
Appearance of Solution (EP)		Clear, Colorless	Clear, Colorless
Chloride	Chloride (NF)	≤ 0.0125 %	< 0.0125 %
	Chloride (EP)	≤ 0.0125 %	< 0.0125 %
	Chloride (JP)	≤ 0.018 %	< 0.018 %
Color and Clarity of Solution (NF)	A720	≤ 0.050	< 0.003
	A420 – A720	≤ 0.100	0.018
Dextrin, soluble starch, and sulfite (JP)		Passes Test	Passes Test
Endotoxin (NF/EP)		≤ 2.4 EU/g	< 0.2 EU/g
Heavy Metals (JP)		≤ 5ppm	< 5 ppm
Identification, IR (NF-A/EP-A/JP-3)		Conforms to Reference Standard	Conforms to Reference Standard
Identification B (NF-B/EP-B/JP-1)		Passes Test	Passes Test
Identification C (NF-C/EP-C/JP-2)		Passes Test	Passes Test
Microbial Content (NF/EP)	*Escherichia coli*	Absent/g	Absent/g
	Salmonella species	Absent/10g	Absent/10g
	TAMC	≤ 100 CFU/g	< 10 CFU/g

ANALYSIS		SPECIFICATION	TEST RESULT
	TYMC	≤ 100 CFU/g	< 10 CFU/g
Nitrogen Determination (NF/JP)		≤ 0.005 %	< 0.005 %
Optical Rotation, Specific Rotation @ 20°C (NF/EP/JP)		+197° to +201°	+ 200 °
pH @ 25°C (NF/EP/JP)		4.5 – 6.5	5.8
Related Substances (NF/EP/JP)	Impurity A	≤ 0.5 %	< 0.10 %
	Impurity B	≤ 0.5 %	< 0.10 %
	Unspecified Impurities	≤ 0.2 %	0.12 %
	Total Impurities	≤ 1.0 %	0.12 %
	Total Impurities with RRT <1.0	≤ 0.5 %	0.12 %
	Total Impurities with RRT >1.0	≤ 0.5 %	< 0.01 %
Residue on Ignition (NF/JP)		≤ 0.1 %	< 0.1 %
Residual Ethanol		≤ 200 ppm	< 95 ppm
Residual Isopropyl Alcohol		≤ 250 ppm	< 135 ppm
Residual Methanol		≤ 50 ppm	< 25 ppm
Soluble Starch (NF/EP)		Passes Test	Passes Test
Sulfated Ash (EP)		≤ 0.1 %	< 0.1 %
Sulfate	Sulfate (NF)	≤ 0.0200 %	< 0.0200 %
	Sulfate (EP)	≤ 0.0200 %	< 0.0200 %
	Sulfate (JP)	≤ 0.024 %	< 0.024 %
Water, KF (NF/EP/JP)		9.0 - 11.0 %	9.7 %

COUNTRY OF ORIGIN: U.S.A.

TEST METHOD REFERENCE: DCN: BSI-ATM-0027

SPECIFICATION STATEMENT: When Applicable, the most stringent monograph specification will be referenced as the specification.

INTENDED USE: Material represented by this Certificate of Analysis is suitable for use as a process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. The material represented by this Certificate of Analysis is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

Prepared by: David McCall Date: 9/29/25 Job Title: QA Tech III

Reviewed by: Jason Vaughn Date: 9/29/25 Job Title: QA Supervisor